Exhibita

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE Attorney Docket No. 94247; 58898/130

In re patent application of

David J. BOVA Group Art Unit:

Serial No.: 08/368,378 Examiner: J. Venkat

Filed: June 14, 1995

For: NICOTINIC ACID COMPOSITIONS FOR TREATING HYPERLIPIDEMIA

AND RELATED METHODS THEREOF

DECLARATION UNDER 37 CFR §1.132 OF DR. ARTHUR RAINES

RECEIVED

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Commissioner of Patents and Trademarks Washington, D.C. 20231

GROUP 1500

Sir:

I, Arthur Raines, Ph.D., state and declare that:

- 1. I am a Professor of Pharmacology at Georgetown University in Washington, D.C. My Curriculum Vitae is appended hereto as Exhibit 1.
- I understand that the examiner of the above-captioned application has maintained a rejection of the claims under 35 USC §102(e), as being anticipated by O'Neill et al., U.S. patent No. 5,268,181 (1993) ("the O'Neill patent"). I also understand that the basis of the rejection is that the O'Neill patent discloses a method of treating hyperlipidemia comprising the administration of a single daily dose of a particular niacin composition, preferably, at, or immediately following, the evening meal, but before bedtime. I further understand that the examiner has taken the position that the administration of niacin in the evening or at night is supported by the parent application of the O'Neill patent (Evanstad et al., U.S. patent No. 5,126,145 (1992)["the Evanstad patent"]), which teaches the administration of niacin In particular, the Evanstad patent states that twice daily. "[t]ablets can be scored to permit dasy [sic] breakage into smaller doses for titration up to the standard 750 mg. dose given twice daily." Evanstad patent at column 5, lines 58-60.

- 3. My review of the Evanstad patent revealed that the patent discloses a formulation of a sustained release tablet suitable for use with highly water soluble drugs, which can present formulation problems. The Evanstad patent describes the use of hydroxypropyl methylcellulose and other ingredients to retard the dissolution of water soluble drugs and thus prolong the period of their absorption. Accordingly, the patent is entitled "Controlled release tablet containing water soluble medicament."
- 4. The Evanstad patent indicates that niacin, which is the water soluble agent used as an example of the invention, could be administered twice a day. See the Evanstad patent at column 5, lines 54-62. According to the patent, the stated purpose of the sustained release is to aid in avoiding side effects (which might occur with a standard tablet dosage form where release usually occurs more rapidly and can lead to headache, dizziness, tingling and flushing). At no point in the patent is the issue of a specified time of administration of niacin mentioned, nor is the issue of diurnal variation in lipid biosynthesis addressed; therefore, the timing of the dose to a particularly appropriate part of the day to enhance efficacy is not a component of the Evanstad patent.
- 5. On the other hand, my review of the O'Neill patent revealed that the document specifically addresses the issue of administering the niacin at a specified time period based on the variation in lipid biosynthesis which occurs over the 24 hour time period. See the O'Neill patent at column 2 (lines 45-53), column 3 (lines 15-22) and column 10 (lines 34-37). The O'Neill patent calls for the taking of the sustained release dosage form at some time with or after the evening meal or at bedtime. This will presumably allow for medication levels to be optimal at the time of peak synthesis of serum lipids.
- 6. In summary, the Evanstad patent does not teach or even suggest the O'Neill method of administering niacin at a time of day targeted to coincide with the time at which cholesterol is

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maximally synthesized in the human liver. The once daily, diurnal variation-related dose of niacin described by O'Neill cannot be said to follow from the two dose, diurnal variation-unrelated regimen of Evanstad.

7. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: May 22, 1996

Arthur Raines

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LAB NO. 0287/31

DATE COLLECTED 06/27/70

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CHLORIDE	104	MF(3/L	95-110
CARBON DIOXIDE CONTENT	24	MEI	9/L	2432
ELECTROLYTE BALANCE	12	Page 1 and 1		5-15
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MUTEROPHILS ARSOLUTE	3.71		15. A 217	Maj 132 - 8130	
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Clinical Laboratories ACCT. NO. Best Available Copy

MS-FLORIDA INC. 6" 4 S MILITARY TRAJE SHESO: the JAY BEACH, FL 33484

TX CONFIGENTIAL REPORT ## ROUTE VIX STOP → S.O.

MMENTS:

LAB NO. 102/(1977)

DATE COLLECTED 07/19/90 #

TIME COLLECTED RESIDENT

- AGE 44 DATE ENTERED 57719790

DATE REPORTED 07/22/90 54376M

REPORT STATUS

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TEST	RESULT	OUT OF RANGE (OR INTERPRETATION)	UNITS	REFERENCE RANGE	sc
TID DISEASE PROFILE		290 11	M670i	0 199	MJ
OSSIBABLE ABULT LIVE	798 (0140 1313)	SEROL (S LESS	GIAN 200 N	6700	,
TRIGLYCERIULS		269 11	MG/IIL	20-160	ĸı
IPOPROTECN, PLENOTYPE INTERPRETATION	-		. <u></u> .		IM
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INTERPRETATION: TYPE	IN PHENOLYS	L.		a many and the	
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ataon mala analy an aminoral management		7728 11 23	HG/DL	POR SALES ENGINEER	MI

CHOLESTEROL, HIGH DENSITY MG/OL

WEB RANGE LEVELS OF HUL CHOLESCERO, AND MAN SULFACER THAN 45 ORDAYER THAN 55

LOU CHOLESTEROL >> REPORT CONTINUED ON NEXT TAGE -

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ES-FLORIDA INC SZA4 S MILITARY TRAIL 5-590 E()Y BEACH. FL 33484

* CONFIDENTIAL REPORT ** ROUTE STOP (EA jour

MMENTS: "TASTING SPECIMEN"

350AM DATE ENTERED

09207012619//34851M

LAB NO. 2502911 PAGE 1 WE THE STATE 09/28/90 TIME COLLECTED AGE 44 М 09/28/90 DATE REPORTED 10/01/90 5:364M REPORT STATUS FINAL

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			inΣ
5	MG/DL	70 - 115	• • • • •
) •	MEIQVE	:35 148	
9	HEOZL	3.5-5.3	
;	MCQ/L	95-110	
	MED/L	24 - 32	
		5-15	
	MG/DL	7-25	
	· MG/III.	0.7-1.4	
		8-30	
•	MG/DL	4.0-8.5	
•	_ MG/JUL	8.5-10.6	
	MOZUL	2.5-4.5	
_	GM/IJL	6.0-8.5	
:	GH/UL	3.2-5.5	
	GHZDL	1.5-3.8	
•		1.1-2.2	
	HEXIL	3.8-4.8	
•	MEZDL	0.2-1.2	
	H/E	20 - 140-	
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	MG/DL	LESS THAN 200	,
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222, H	MG/IIL "	20-160-	
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W - 4.0			ΗI
<u> </u>	THOUSAND/CU	J.MM.3.8 - 10.8	
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Clinical Laboratories

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TIME COLLECTED

2502921 DITE COLLEGE - 08/30/90 ...

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FES ELORIDA INC

14244 S MILITARY TRAIL S-590 RAY BEACH, FL 33484

ACCT. NO.

08/30/90 DATE ENTERED DATE REPORTED

08/31/90

0800

5:27AM

** CONFIDENTIAL REPORT ** 00

W3 stop 1.60ROUTE

FINAL REPORT STATUS

003090117137620951F

MMENTS:

TEST	RESULT	OUT OF RANGE (OR INTERPRETATION)	UNITS	REFERENCE RANGE
HEMZYME PLUS/CBC/UA				
CHEMZYME				
GLUCOSE []	89		MG/DL	80 - 125
SCDIUM	1.42		MEQZL	135-148
POTASSIUM	4.3		MEQ/L	3.5-5.3
CHLORIDE	104		MidQ./1.	95-110
CARBON DIOXIDE CONTENT	28		MEQ/L	24 - 32
ELECTROLYTE BALANCE	1.0			5-15
UREA NITROGEN	17		MG/DL	7-25
ONEATININE	1.2		MG/DIL	0.7-1.4
BUN/CREATININE RATIO	14			8-20
URIC ACID	3.4		MGZDL -	2.5 - 7.5
CALCIUM	7.6		MG/DL	8.5-10.6
PHOSPHORUS, INCAGANIC	3.9		MG/III	2.5-4.5
PROTEIN. TOTAL	6.9	41	GM/DL	6.0-B.5
ALBUMTN	3.7		GM/DL	3.2-5.5
GLOBULIN	3.0		GM/DL	1.5-3.8
A/G RATIO	1.3		of it issued a company to the second	1.1-2.2
CALCIUM, TONIZED	4.3		MG/DL .	77378-478-77
BILIRUBIN, TOTAL	0.5		MG/DL	0.2-1.2
ALKALINE PHOSPHATASE,			The second second	د په په در مورد استوال در
TOTAL	77	Silleren with	U/L	20 - 140
LACTATE DEHYDROGENASE ASPARTATE TRANSAMINASE	126	€ ing	サイド	0 - 250
ALANINE AMINOTRANSFERASE	22		U/L	0-50
(SGPT)	14		U/L	0 - 55
G VINDER OF THE STREET		ce	MG/DL	0 - 199
DESTRABLE ADULT LEVEL FO	R CHOLES	TEROL IS LESS	THAN 200 MG	7DL.
TRIGLYCERIDES		239 H	MG/DL	20-190
IRON, TOTAL	66	A	HEG7DE	40 - 150
CECT. PENTENESS .		115		And the state of t
WHITE BLOOD CELLS		3.7 L	THOUSAND/CU	.MM.3.8 - 10.8
RED BLOOD CELLS	4106		HILLIONS/CU	-ин-3 .90 - 5.20-
HEMOGLOBIN (B)	12.3		GMZDL	12.0 - 15.6
HEMATOCRIT	36.5		%	35.0 - 46.0
MCV	59.9	· ·	FEMTOLITERS	80.0 - 100.0
MCH 18 Andrew Assessment of the control of the cont	30.3	·		- 27.0 - 33.0
MCHC	33.8		7.	32.0 - 36.0
RDW	10.8			10.0 - 15.0
FLATELET COUNT		سطري بيا يا ساميوسي چا		.MM.130 - 400
	1.4.1 50	•	7 HOUSHIED CO	40 - 75
NEUTROPHILS	- P			

Clinical Laboratories

LAB NO. 2502756

DATE COLLECTED 09/04/90

AGE

PAGE

TIME COLLECTED 0900

09/04/90

56 SEX

DATE ENTERED DATE REPORTED 09/05/90

REPORT STATUS FINAL

5:19AM

* CONFIDENTIAL REPORT **

4Y BEACH, FL 33484

6244 S MILITARY TRAIL S-590

EA 00

ROUTE \$43 STOP 3:50

"FASTING SPECIMEN" MMENTS:

ES-FLORIDA INC

09049011342/3325898

TEST	RESULT	OUT OF RANGE (OR INTERPRETATION)	UNITS	*	REFERENCE RANGE	sc
A.R.E. PANEL #2 CHOLESTEROL, TOTAL	÷		MG/DL		- 199	m.i
					* * * * * * * * * * * * * * * * * * * *	1 1
DESIRABLE ADULT LEVEL FOR	R CHOLES	TEROL-IS LESS	THAN 200 M	(G ∠(0L.•		
•	_				() p	71.
TRIGLYCERIDES	(234 H	MG/DL	20-	-190	. MI
e de la companya del companya de la companya del companya de la co	,					HI
CHOLESTEROL, HIGH DERSITY		(35 L)	MG/DL			
LIPOPROTEIN		33 L	MO/ DC		The state of the same statement	Hand of the Control o
DESIRABLE LEVELS OF HDL	CHOLESTER				The same of the sa	
- manageryagan and in managericans and appear of purposes. The second of		FEMALE	E GREATER	IHAN	55	-
LUL CHOLESTEROL	(165 H	MG/IL	LES	S THAN 13	0
	`				the second control of	
CHOLESIEROL ZHDL. RATIO	7.06		A Marketin Same of the American American	** .		3
	7.06	********	A september of the second seco	·	The second secon	
CHOLESIERO ZHDE RATIO ***********************************	******	******	A SAN SAMARA		agramme of the particular control of	
CHOLESIEROL/HDL RATIO	******** EASE RISH	******				
CHOLESTERO /HDL. RATIO ****************** CORONARY HEART DISH RELATIVE RISK	******* EASE RISH T/HDL CI	********* TABLE	American Service Control of the Cont			
CHOLESTEROL/HDE.RATIO ***************** CORONARY HEART DISK RELATIVE RISK MEN 0.5 AVERAGE	******* EASE RISH T/HDL CI	********* TABLE HOL RATIO				
CHOLESIEROL/HDE RATIO ***************** CORONARY HEART DISC RELATIVE RISK MEN 0.5 AVERAGE AVERAGE	******* EASE RISH T/HDL CH	**************************************				
CHOLESTEROL/HDL.RATIO ***************** CORONARY HEART DISH RELATIVE RISK MEN 0.5 AVERAGE AVERAGE 2 X AVERAGE	******* FASE RISH T/HOL CH	**************************************				
CHOLESIEROL/HDE RATIO ***************** CORONARY HEART DISC RELATIVE RISK MEN 0.5 AVERAGE AVERAGE	******* FASE RISH T/HOL CI	**************************************		700		
CHOLESTEROL/HDL.RATIO ****************** CORONARY HEART DIST RELATIVE RISK MEN 0.5 AVERAGE AVERAGE 2 X AVERAGE 3 X AVERAGE WOMEN 0.5 AVERAGE	******* FASE RISH T/HOL CI	**************************************				
CHOLESTEROL/HDL.RATIO ****************** CORONARY HEART DISH RELATIVE RISK MEN 0.5 AVERAGE AVERAGE 2 X AVERAGE 3 X AVERAGE AVERAGE AVERAGE AVERAGE AVERAGE AVERAGE AVERAGE	******** EASE RISH T/HDL CI	**************************************				
CHOLESTEROL/HDL.RATIO ****************** CORONARY HEART DIST RELATIVE RISK MEN 0.5 AVERAGE AVERAGE 2 X AVERAGE 3 X AVERAGE 2 X AVERAGE	******* EASE RISH T/HDL CI	**************************************				
CHOLESTEROL/HDE.RATIO ***********************************	******* EASE RISH T/HDL CI	**************************************				
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CHOLESTEROL/HDE.RATIO ***********************************	******* EASE RISH T/HDL CI	**************************************				
CHOLESTEROL /HDE. RATIO ***********************************	**************************************	**************************************				

INDICATES TESTING SITE SEE REVERSE SIDE T

Clinical Laboratories

ACCT. NO. 254 Best Available Copy LAB NO. 2502782

S-FLORIDA INC

3244 S'MILITARY TRAIL 5-590 T Y BEACH, FL 33484

< CONFIDENTIAL REPORT ** ROUTE 设置 STOP 1点点 AMENTS:

DATE 09/07/90

TIME COLLECTED 0800 DATE ENTERED

09/07/90 DATE REPORTED 09/08/90

REPORT STATUS FINAL

090790121007651675P .

56 9:03AM

TEST	RESULT	OUT OF RANGE	UNITS	REFERENCE	
F. PANEL #2		(OR INTERPRETATION)		RANGE	
LESTEROL, TOTAL	ثے	MG	/ Dil_	LESS THAN 200	भ्रा
200 - 239 MG/DL IS	BORDERLINE I		RS OLD OR G		11.1
	_				
GLYCERIDES		243 H MG/	/DU_	20-190	MI
	• 0	•			MI
HULESTEROL: BIGH DEMO	, fY				
LIPOPROTEIN	<u></u>	35 L MG/	e Eul		
DESIRABLE LEVELS OF H	N CHOLESTER	OL AREL MALE	GREATER TH	AN. 45.	
		FEMALE	GREATER TH		
DL CHOLESTEROL	<u></u>	186 H. MG	/Id	LESS_THAN_130	برسمها
CHOLESTEROL/HOLL BATIO	7.71			ar ay ayri maan ayaayaa maraasa waxaa	
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AVERAGE		.97		A CONTRACTOR OF THE PROPERTY O	
2 X AVERAGE	9.	NOT ?	ja nya majijyaa iliji namaanaa ya bara. Madaa ka waxaa ka Aisaankii waxaa ka a waxaa	eje i o soloso sa i s M	
3 X <u>A</u> VERAĢE	23	.39		,	
WOMEN 0.5 AVERAGE	* -	. 27	- Carlola)	
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	7	.05	. ~ "		
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11/12/90

TIME COLLECTED 830 DATE ENTERED

11/12/90 DATE REPORTED

11/13/90 5:16AM PAGE 1

REPORT STATUS FINAL

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* CONFIDENTIAL REPORT **

_ .AY BEACH, FL 33484

NEUTROPHILS, ABSOLUTE

LYMPHOCYTES, ABSOLUTE

MONOCYTES, ABSOLUTE

NEUTROPHILS

LYMPHOCYTES

MONOCYTES

1744 S MILITARY TRAIL 5-590

A 00

ES-FLORIDA INC

ROUTE W3 STOP 160

#MENTS: "FASTING SPECIMEN"

TEST	RESULT	OUT OF RANGE (OR INTERPRETATION)	UNITS	REFERENCE RANGE	sc
HEMZYME PLUS/CBC/UA					
CHEMZYME					MI
GLUCOSE	103		MG/DL	70 - 115	
SODIUM	144		MEQ/L	135 - 148	
POTASSIUM	3.8		MEQ/L .	3.5 - 5.3	
CHLORIDE	104		MEQ/L	95 - 110	
CARBON DIOXIDE CONTENT	28 -		MEQ/L	24 - 32	
ELECTROLYTE BALANCE	12	•		5-15	
UREA NITROGEN	19		MG/DL	7 - 25	
CREATININE	1.2		MG/DL	0.7 - 1.4	
BUN/CREATININE RATIO	16		k g 796	8-20	
URIC ACID	4.2		MG/DL	2.5 - 7.5	
CALCIUM	9.3	*	MG/DL	8.5 - 10.6	
PHOSPHORUS, INORGANIC	3.5		MG/DL	2.5-4.5	
PROTEIN, TOTAL	6.7		GM/DL	6.0-8-5	
ALBUMIN	3.8	`	GM/DL	3.2-5.5	
GLOBULIN, TOTAL	2.9	No.	GM/DL-	1.5-3.8	
A/G RATIO	1.3			1.1-2.2	
CALCIUM, IONIZED	4.2		MG/DL-	3.8-4.8	
BILIRUBIN, TOTAL	0.7		MG/DL	0.2 - 1.2	
ALK PHOS, TOTAL	81		UYE	20 140	
LACTATE DEHYDROGENASE	147	11	U/L	0 250	•
AST (SGOT)	an and an area on an area.	52 H N	U/L	0-50	
ALI (SGPT)	46		U/L	0 - 55	
	and the same and t		MG/DL	LESS THAN 200	
200 - 239 MG/DL IS BO	RDERLINE H	IGH FOR 20 Y			
TRIGLYCERIDES				20-160	
IRON, TOTAL	48		MCG/IL	40 - 150	
en en entre en	and the second s				
COMPLETE BLOOD CT & DIFF	***	,			MI
WHITE BLOOD CELLS	5,2	Markanian in the contract of	THOUSAND/CU.	MM-3-8 - 10-8	
RED BLOOD CELLS	4.40		MILLIONS/CU.	MM.3.90 - 5.20	
	13-2	Same of the same o		12-0-15-6	
HEMATOCRIT	39.2		%	35.0 - 46.0	
MCV.	89.0	Maria de la companya del companya de la companya de la companya del companya de la companya de l	c cath the many contributes for the	80.0100.0	
MCH	30.0	· · · · · ·	PICOGRAMS	27.0 - 33.0	
MCHC	33-7	redor.	%	32.0 - 36.0	
RDW	12.5		UNITS	10.0 - 15.0	
PLATELET COUNT	142			MM-130 - 400	
I WITTERE I COUNTY				AA 75	

EOSINOPHILS >> REPORT CONTINUED ON NEXT PAGE <<

2.78 ---

1.88

0.28

53

37

6

3

%

%

INDICATES TESTING SITE SEE REVERSE SIDE T

40 - 75

18 - 47

0 - 10

THOUSAND/CU-MM-1-52 - 8.10

THOUSAND/CU.MM.0.68 - 5.07

THOUSAND/CU.MM.0.10 - 1.08

PES-FLORIDE INC 16244 S MILITARY TRAIL S-590 DECAY BEACH, FL 33484

** CONFIDENTIAL REPORT **

AREA OO

ROUTE W3

STOP 160

COMMENTS: FASTING

Clinical Laboratories

LAB NO. 2502801

DATE COLLECTED 09/19/90

TIME COLLECTED 0830



AGE 47 SEX M

7:44AM

DATE ENTERED 09/19/90
DATE REPORTED 09/20/90
REPORT STATUS FINAL
09199011339/702808P

TEST	RESULT	OUT OF RANGE (OR INTERPRETATION)	UNITS	REFERENCE RANGE	S
CHEMZYME PLUS/CBC/UA	·				
GLUCOSE					MI
SODIUM	97	MG/	DL	70 - 115	
POTASSIUM	139	MEQ.	/L	135-148	
	4.2	MEQ.	/L	3.5-5.3	
CHLORIDE	103	, MEQ.	/L	75-110	
CARBON DIOXIDE CONTENT	27	'MEQ	/L	- 24 - 32	
ELECTROLYTE BALANCE	9	,ŧ		5-15	
UREA NITROGEN	13	MG/1	DL	7-25	
CREATININE	1.2	`MG/I	DE_	0.7-1.4	
BUN/CREATININE RATIO	11	to the second second		8-20	
URIC ACID	ర•ర	MG/I	iL.	4.0-8.5	
CALCIUM	8.9	MG/I		8.5-10.6	
PHOSPHORUS, INORGANIC	2.8	MG/I		2.5-4.5	
PROTEIN, TOTAL	5.7	GM/I		6.0-8.5	t Arreira i
ALBUMIN	4.0	GM/I	n a beneg the .	3.2-5.5	** ***
GLOBULIN	2.7	GM/I		1.5-3.8	ens. e e esser
A/G RATIO	1.5	which is the second	T	1.1-2.2	e
TALCIUM, IONIZED	4.0	MG71	TL.	3.8-4.8	
BILIRUBIN, TOTAL	0.6	MG/I		0.2-1.2	
ALK PHOS, TOTAL	55	and distance and a second seco		20 - 140	
LACTATE DEHYDROGENASE	125	U/L	***************************************	0 - 250	
AST (SGOT)	21	UZC		0-50 J	
ALT (SGPT)	22	U/L	no compressor.	0 - 55	
		MRZT			
200 - Zay Mozal IS BO	RUERLINE H			LESS THAN 200 GREATER	
INTOLICERIDES		162 H MG/D		20-160	
IRON, TOTAL	102	MCG/	An an beigne in	40 - 150	
		The second secon		40 - 100	-
COMPLETE BLOOD CT & DIFF	· Phonestone and Little Control of the Control of t		Medical from subset	the second section of the s	W.7
WHITE BLOOD CELLS			RAMETER	Mins.8 - 10.8	MI
RED BLOOD CELLS	4.49	MI	TONS/CU		
HEHOGEOS IN (B)	19.8	VIO. (1)			
HEMATOCRIT		40.1 L		13.8 17.2 41.0 - 50.0	·
	STREET,				r (alle (manage) organ gr
мсн	30.6	PICO	GRAMS	260300=5100405	. I
HOLES OF THE PARTY	34.3			27.0 - 33.0	
RUW.	11.8	UNIT		32.0 - 36.0	•
PLATELET COUNT	175			10.0 - 15.0	_
NEUTROPHILS	51		SUMPACA	MM.130 - 400	
NEUTROPHILS, ARSOLUTE	2139		Treconi Lacc	40 - 75	
LYMPHOCYTES	39	TEROS	SANDICU	Mt. 1.52 - 8.10	- 155
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